FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 19 November 2009 in which the specification and claims 1 and 17 were amended, claims 3-4 and 9 were canceled, and new claims 18-19 were added. All of the amendments have been thoroughly reviewed and entered.

The previous objections to the specification and drawings not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed below.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Election/Restrictions

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Each SEQ ID NO of SEQ ID NOS: 1-7 is a distinct species.

3. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

4. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Claims 18-19 are drawn to the distinct species of each of SEQ ID NOS: 1-7.

The following claim(s) are generic: 1-17.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The sequences listed encompass

different genes from different organisms. Moreover, since the sequences are not homologous to each other, they fail to share a common structure; i.e., a significant structural element. The sugar-phosphate backbone cannot be considered a significant structural element, since all nucleic acids molecules share it. Therefore, the genes do not share any significant structural element and cannot be considered as having the same or corresponding technical feature.

7. During a telephone conversation with James P. Kastenmayer on 17 February 2010, a provisional election was made without traverse to prosecute the invention of the combination of all SEQ ID NOs: 1-7. Affirmation of this election must be made by applicant in replying to this Office action. No claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Withdrawal of Election/Restrictions

8. Upon further search and consideration, the Requirement for Restriction is hereby withdrawn.

9. Claims 1-2, 5-8, 10-12, and 17-19 are under prosecution.

Drawings and Specification

10. As noted in the previous Office Action, the amendments to the Drawings filed 28 July 2006 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

A. New Figures 15 and 16 are objected to under 35 U.S.C. 132(a) because they introduce new matter into the disclosure. While pages 43-44 of the National Stage entry of the specification as originally filed contain a generic description of Figures 15 and 16, and while page 36 of the PCT Application Publication No. WO 2005/073403 A1 refers generically to "Abbildungen 15 und 16," the PCT Application as originally filed does not contain Figures (i.e., "Abbildungen") 15 or 16. Therefore, the specific embodiments depicted in Figures 15 and 16 were not present in the PCT as originally filed, and each of Figures 15 and 16 therefore constitute new matter.

B. Applicant is required to cancel the new matter in the reply to this Office Action.

C. It is noted that in response to the previous Objection to new Figures 15-16, Applicant states on pages 9-10 of Applicant's arguments filed 19 November 2009 (hereafter the "Remarks") that "Applicant has cancelled claims 15 and 16 and requests that the Office withdraw the objection." This appears to be a typographical error because it is **Figures** 15-16 that need to be cancelled, not **claims** 15-16.

D. Applicant is reminded that if a drawing figure is canceled, a replacement sheet of drawings must be submitted without the figure. See MPEP 608.02(t). Because Applicant has not cancelled Figures 15-16 in accordance with MPEP 608.02(t), the objection is maintained.

11. With regards to the remaining objections to the specification listed in the previous Office Action:

A. The objections to the amendments to pages 1 and 63 are withdrawn in view of Applicant's amendments filed 19 November 2009.

B. The objections to the amendments to page 68 of the specification are withdrawn in view of Applicant's arguments filed 19 November 2009 (hereafter the "Remarks").

Claim Interpretation

12. As noted in the previous Office Action, claims 1-12 are drawn to a "system." As noted in the previous Requirement for Restriction mailed 25 February 2009, the specification teaches a "system" wherein the "system" is defined in terms of **structural** limitations (e.g., page 4). In addition, claims 1-12 recite **structural** limitations of the "system." Thus, the "system" is interpreted to encompass any collection of reagents and parts used together that are not necessarily part of a completely integrated single unitary device. Any further interpretation of the word is considered an "intended use" and does not impart any further structural limitation on the claimed subject matter.

13. The following rejections are new rejections new rejections necessitated by the amendments.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-2, 5-8, 10, 12, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurn (U.S. Patent Application Publication No. US 2002/0115088 A1, published 22 August 2002).

Regarding claim 1, Kurn teaches an analytical test system comprising a molecular switch; namely, the system comprises a probe in the form of an oligonucleotide probe and a catalytic component in the form of an interacting label pair (paragraph 0049). The catalytic component is inhibited when the molecular switch is bound to an analyte; namely, the catalytic component (i.e., label pair) comprises subunits of an enzyme which are dissociated upon binding of the analyte, thus resulting in a decrease in the rate of the reaction catalyzed by the enzyme (i.e., the enzyme is inhibited; paragraph 0064).

Regarding claim 2, Kurn teaches the system of claim 1, wherein the probe is directly conjugated to the catalytic component; namely, the catalytic component (i.e., the

moieties of the interacting label pair) are directly attached to the probe via a covalent bond (paragraphs 0091-0092).

Regarding claims 5-8, Kurn teaches the system of claim 1, wherein the probe is an oligonucleotide (i.e., claim 8; paragraph 0094), which is a nucleic acid (i.e., claim 5; paragraph 0094) in the form of DNA, RNA, or PNA (i.e., the deoxyribonucleic acid, ribonucleic acid, and peptide nucleic acid of claim 6; paragraph 0097). The probe is also present in hybridized form (i.e., claim 7; paragraph 0102).

Regarding claims 10 and 12, Kurn teaches the system of claim 1, wherein the catalytic component is an enzyme; namely, the catalytic component (i.e., label pair) comprises subunits of an enzyme which are dissociated upon binding of the analyte, thus resulting in a decrease in the rate of the reaction catalyzed by the enzyme (i.e., the enzyme is inhibited; paragraph 0064).

Regarding claim 17, Kurn teaches a molecular switch comprising a probe in the form of an oligonucleotide probe and a catalytic component in the form of an interacting label pair (paragraph 0049). The catalytic component is inhibited when the molecular switch is bound to an analyte; namely, the catalytic component (i.e., label pair) comprises subunits of an enzyme which are dissociated upon binding of the analyte, thus resulting in a decrease in the rate of the reaction catalyzed by the enzyme (i.e., the enzyme is inhibited; paragraph 0064).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1 and 10-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Kurn (U.S. Patent Application Publication No. US 2002/0115088 A1, published 22 August 2002) in view of Lizardi (U.S. Patent No. 5,118,801, issued 2 June 1992).

It is noted that this rejection applies to claim 1 to the extent that it is drawn to the embodiments of dependent claims 10-11.

It is also noted that while claim 10 has been rejected under 35 U.S.C 102(b) as described above in Section 15, the claim is also obvious using the interpretation outlined below.

Regarding claims 10-11, Kurn teaches the analytical test system of claim 1, which comprises a molecular switch; namely, the system comprises a probe in the form of an oligonucleotide probe and a catalytic component in the form of an interacting label pair (paragraph 0049). The catalytic component is inhibited when the molecular switch is bound to an analyte; namely, the catalytic component (i.e., label pair) comprises subunits of an enzyme which are dissociated upon binding of the analyte, thus resulting in a decrease in the rate of the reaction catalyzed by the enzyme (i.e., the enzyme is inhibited; paragraph 0064).

Kurn does not explicitly teach the catalytic component is a catalytically active nucleic acid (i.e., claims 10-11).

However, Lizardi teaches a molecular switch comprising a probe and a catalytic component; namely, Lizardi teaches Figures 12-13, which show a probe in the form of a probe sequence 31 and a catalytic component in the form of an pre-ribozyme sequence 32 (Example V), wherein the binding of a target to the probe results in a conformational switch that activates ribozyme 36 (Figure 13 and Example V). A ribozyme is a catalytically active nucleic acid (i.e., claim 10; column 13, lines 5-20), and is made of ribonucleic acid (i.e., claim 11). Lizardi also teaches the ribozyme has the added advantage of releasing an exponentially replicatable signal component (Example V), which has the benefit of increasing the sensitivity of detection (column 8, lines 40-50). Thus, Lizardi teaches the known technique of using a catalytically active nucleic acid.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the system as taught by Kurn so that the catalytic component is the catalytically active nucleic acid as taught by Lizardi to arrive at the instantly claimed system with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a system having the added advantage of increasing the sensitivity of detection as a result of releasing an exponentially replicatable signal component as explicitly taught by Lizardi (Example V and column 8, lines 40-50). In addition, it would have been obvious to the ordinary artisan that the known technique of using a catalytically active nucleic acid as a catalytic component on the probe as taught

by Lizardi could have been applied to the system of Kurn with predictable results because the known technique of using a catalytically active nucleic acid as a catalytic component on the probe as taught by Lizardi predictably results in the use of a reliably detectable catalytic component.

18. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurn (U.S. Patent Application Publication No. US 2002/0115088 A1, published 22 August 2002) in view of Nadeau et al (U.S. Patent No. 5,882,870, issued 16 March 1999).

It is noted that this rejection applies to claim 17 to the extent that it is drawn to the embodiment of dependent claim 18.

Regarding claim 18, Kurn teaches the molecular switch of claim 17, which comprises a probe in the form of an oligonucleotide probe and a catalytic component in the form of an interacting label pair (paragraph 0049). The catalytic component is inhibited when the molecular switch is bound to an analyte; namely, the catalytic component (i.e., label pair) comprises subunits of an enzyme which are dissociated upon binding of the analyte, thus resulting in a decrease in the rate of the reaction catalyzed by the enzyme (i.e., the enzyme is inhibited; paragraph 0064).

Kurn does not teach SEQ ID NO. 4.

However, Nadeau et al teach the sequence of SEQ ID NO. 4 (SEQ ID NO; 2 of Nadeau et al), which has the added advantage of being useful for the reversible anticoagulation of blood (claim 1 of Nadeau et al). The additional sequence is

encompassed by the open claim language "comprising" found in the instant claims. Thus, Nadeau et al teach the known technique of using SEQ ID NO. 4.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the switch as taught by Kurn so that the sequence of the switch comprises SEQ ID NO. 4 of Nadeau et al to arrive at the instantly claimed switch with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a switch having the added advantage of being useful for the reversible anticoagulation of blood as explicitly taught by Nadeau et al (claim 1 of Nadeau et al). In addition, it would have been obvious to the ordinary artisan that the known technique of using the sequence of Nadeau et al could have been applied to the switch of Kurn with predictable results because the known technique of using the sequence of Nadeau et al predictably results in a sequence useful in reversible anticoagulation of blood.

19. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurn (U.S. Patent Application Publication No. US 2002/0115088 A1, published 22 August 2002) in view of Nadeau et al (U.S. Patent No. 5,882,870, issued 16 March 1999) as applied to claim 18 above, and further in view of Durkop (U.S. Patent Application Publication No. US 2002/0137027 A1, published 26 September 2002).

Regarding claim 19, the switch of claim 18 is discussed above in Section 18.

Neither Kurn nor Nadeau et al teach the catalytic component is galactose oxidase.

However, Durkop teaches labeling of nucleic acid oligomers with oxidases (paragraph 0061), wherein the oxidase is galactose oxidase (paragraph 0201). Durkop teaches oxidases have the added advantage of allowing quantitative detection upon addition of only a single additional reagent (paragraph 0026). Thus, Durkop teaches the known technique of using galactose oxidase as a catalytic component.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the switch as taught by Kurn in view of Nadeau et al so that the catalytic component is galactose oxidase in accordance with the teachings of Durkop to arrive at the instantly claimed switch with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a switch having the added advantage of allowing quantitative detection upon addition of only a single additional reagent as explicitly taught by Durkop (paragraph 0026). In addition, it would have been obvious to the ordinary artisan that the known technique of using galactose oxidase as taught by Durkop could have been applied to the switch of Kurn in view of Nadeau et al with predictable results because the known technique of using galactose oxidase as taught by Durkop predictably results in a catalytic component useful for detection in nucleic acid assays.

Response to Arguments

20. Applicant's arguments with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Allowable Subject Matter

21. The following is a statement of reasons for the indication of allowable subject matter: SEQ ID NOS 2-3 and 6-7 are found to be free and clear of the prior art.

Conclusion

22. No claim is allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Primary Examiner
Art Unit 1634

/Robert T. Crow/
Primary Examiner, Art Unit 1634